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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,610	09/26/2001	Adam S. Cantor	56032US022	8132

32692 7590 12/19/2005

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/965,610	CANTOR ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,16-18,28-31,35-37 and 39-91* is/are pending in the application.

4a) Of the above claim(s) *48-53 and 55-91* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,16-18,28-31,35-37,39-47 and 54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. 10/05 .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment, filed 10/13/2005.

Claims 1-9, 16-18, 28-31, 35-37 were previously presented. Claims 39-91 have been added.

Newly submitted claims 48-53, and 55-91 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 48-53 and 55-91 do not require the copolymer comprising two monomers (i) alkyl acrylate monomer and (ii) ethylenically unsaturated monomer as required by claims 1, 35-37 and 54. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, **claims 48-53 and 55-91 are withdrawn** from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-9, 16-18, 28-31, 35-37, 39-47 and 54 are included in the prosecution.

Interview Summary

During a telephone conversation with applicants' representative on October 2005, applicants' representative indicated the possible interference of the amended claims with the claims of U.S. application 10/850,865. However, none of current pending claims under prosecution found allowable, and allowability of the claims should be determined before determination of interference.

The following rejection has been discussed in details in previous office action, and maintained for reasons of record:

Claim Rejections - 35 USC § 112

1. Claims 1-9, 16-18, 28-31, 35-37, 39-47 and 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The expression "substantially free" does not set forth the metes and bounds of the claim. Recourse to the specification does not define the expression.

Response to Arguments

2. Applicant's arguments filed 10/13/2005 have been fully considered but they are not persuasive. Applicants traverse indefinite rejection by arguing that the specification states that the presence of undissolved fentanyl may be detected by examination with an optical microscope at 20x magnification, thus, "substantially free" is one in which

examination with an optical microscope at 20x magnification yields no evidence of dispersed fentanyl.

In response to this argument, the examiner position is that applicant do not set forth scope for the range of "substantially free". In the specification page 7, last paragraph, applicants only disclose that: "The presence of undissolved fentanyl may be detected by examination with an optical microscope at 20x magnification". However, applicants do not disclose range for the undissolved fentanyl that is considered as "substantially free" in order to determine if the composition is substantially free or not free from undissolved fentanyl. Applicants merely disclose how to detect the undissolved fentanyl.

The following new ground of rejection is necessitated by applicants' amendment:

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-9, 16-18, 28-31, 35-37, 39-47 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/08229 ('229) in view of US 5,993,849 ('849).

WO '229 teaches a transdermal drug delivery device comprising a backing and a matrix comprising a copolymer, a softener and a drug (page 2, lines 5-23). The copolymer comprises 40-90% of one or more A monomers selected from the group consisting of alkyl acrylates containing 4 to 10 carbon atoms in the alkyl group and alkyl methacrylates containing 4 to 10 carbon atoms in the alkyl group and up to 60% of one or more ethylenically unsaturated B monomers copolymerizable with the A monomers. The composition further comprises more than 30% of a macromonomer copolymerizable with the A and B monomers (page 2, lines 5-23). The A monomers are taught on page 4, lines 3-14 with isooctyl acrylate preferred. The B monomers are taught on page 4, line 15 through page 5, line 12, with hydroxyethyl acrylate preferred. The macromonomers are taught on page 5, line 13 through page 8, line 28. Polymethylmethacrylate macromonomers are preferred (page 6, lines 17-18). The softeners of the delivery device affect skin penetration rate and include fatty acids, fatty alcohols, fatty acid esters such as methyl laurate and tetraglycols (page 8, line 29 -

page 10, line 15). Softeners can be included in amounts up to 60% by weight of the matrix (page 10, lines 7-15). WO '229 further contemplates various drugs for delivery by the device including analgesics such as fentanyl (page 12, line 28). The drug is present in the transdermal device in an amount of about 0.01 to about 30 percent by weight (page 13, lines 16-18). Also, the drug is substantially fully dissolved, and the matrix is substantially free of solid undissolved drug (page 13, line 18-20).

However, WO '229 does not specifically exemplify that fentanyl is the drug delivered by the disclosed composition, the reference exemplifies nicotine and levonorgestrel. Fentanyl is listed as a possible acceptable drug for transdermal delivery by the disclosed transdermal copolymer composition.

US '849 teaches adhesive composition suitable for transdermal delivery systems and having improved tolerance on the skin and improved controlled release of the active substance (abstract; col.2, lines 15-19). The composition comprises acrylate copolymer and drug exemplified by fentanyl and nicotine (claim 10). Therefore the art recognized the equivalency between nicotine and fentanyl as drugs suitable for transdermal delivery in an acrylate copolymer composition.

Therefore, it would have been obvious to one having ordinary skill in the art at the of the invention to provide transdermal delivery composition comprising copolymer of alkyl acrylate monomer and ethylenically unsaturated monomer as disclosed by WO '229, and use the composition to deliver fentanyl because the art recognized the equivalency between nicotine exemplified by WO '229 and fentanyl as claimed by US '849, motivated by the teaching of US '849 that the transdermal delivery system

disclosed to deliver fentanyl and nicotine has improved tolerance on the skin and improved controlled release of the active substance with reasonable expectation of having transdermal delivery composition comprising copolymer of alkyl acrylate monomer and ethylenically unsaturated monomer that deliver fentanyl at improved controlled release rate and meanwhile has improved tolerance on the skin.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

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